REMARKS

The Office Action mailed 24 July 2008 has been received and considered.

CLAIM OBJECTIONS:

Claim 2 has been objected to in view of the use of the phrase "non cutting." Responsive to the Examiner's objection, applicant has amended the language of Claim 2 to delete the objected to phrase. In view of this amendment, applicant respectfully requests the withdrawal of the objection to Claim 2.

CLAIM REJECTIONS 35 U.S.C. § 102:

Claims 1-4, 6, 8, 9, 12, 14-18, 20, 23, 25 and 27 stand rejected as being allegedly anticipated under 35 U.S.C. 102(b) over Zohmann. Applicant respectfully traverses the rejection.

As amended, Claim 1 provides a flexible spinal needle cathter assembly which is adapted for inserting a catheter into a patient. The assembly includes three principal components, namely a flexible needle catheter 15, a hollow support needle 19 and a central stylet 17. The stylet 17 is releaseably positioned within a lumen defined within the hollow support needle 19. The stylet 17 is dimensioned to close an opening 28 defined within the sidewall of the hollow support needle 19, thereby precluding the entry of material into the lumen defined within the support needle 19. The hollow support needle 19 defines a pencil point, non-cutting tip 27 which is configured for penetrating the patient while not cutting the dura mater tissue of the patient. The pencil point tip pushes aside the fibers of the dura mater without cutting those fibers. Specifically, the "pencil point" tip is configured to open a puncture hole in the patient of sufficient dimension to permit the flexible needle catheter assembly to be inserted and positioned within the patient while also limiting the dimensions of that hole such that upon removal of the assembly from the patient the dura mater of the patient may readily reseal the puncture hole. The hollow support needle 19 is disposed within a hollow bore defined within the flexible needle catheter 15. The flexible needle catheter 15 is releaseably secured on the exterior of the support needle. As the support needle is inserted into the dura mater of a patient the catheter is carried along by the support needle, The leading edge of the catheter is secured proximate the tip of the support needle. Soon after the tip of

support needle. Soon after the tip of the support needle penetrates the dura mater, the leading edge of the catheter likewise penetrates the dura mater. The leading edge is tapered so that it substantially has a diameter corresponding to the exterior diameter of the needle support. As the pencil point enters the dura mater by pushing aside the fibers of the dura mater, the tapered catheter continues that "pushing aside" action as the catheter is carried into the dura mater by the support needle. Similar to the support needle tip, the catheter, due to its shape likewise does not cut the dura mater tissue. It follows that the instant assembly provides a structure for inserting a catheter into the dura mater without cutting the tissue of the dura mater. Given the positioning of the flexible needle catheter 15 on the exterior of the support needle 19 and the configuration of the flexible needle catheter, the instant assembly provides a structure adapted for more efficiently installing catheters having larger diameters than prior catheter installation devices while at the same time reducing the danger of minimizing the danger of PDPH.

Applicant respectfully submits that the Zohmann reference does not disclose the structural components of applicant's claimed assembly.

Zohmann discloses an assembly which includes a stylet 30 which is disposed within a needle component 4. The needle component 4 defines a rounded tip 54 and an opening 53, which is configured for providing access to the hollow interior of the needle component. The needle component 4 is disposed within a hollow channel defined within an introducer 6. The introducer 6 has a beveled leading edge which is configured for puncturing the patient and thereby defining an entry hole through which the body of the assembly may be subsequently inserted into the patient. See col. 8, lines 44-46. In the Zofmann method, once the introducer has penetrated the patient, the needle component 4 is advanced through the channel of the introducer and thereafter the needle component 4 is brought into contact with the dura mater. The needle component is then urged through the dura mater. Col. 8, lines 45-47. The medicating agent is then injected into the dura mater through the needle component 4. In the Zohmann device, the medicating agent is to be introduced into the patient through the hollow needle 4 after the stylet 2 has been withdrawn from the interior of the needle 4. See col. 7, lines 24-25. Notably, Zofmann contains no disclosure that the introducer 6 actually enters the dura mater. Instead, the introducer functions solely to initially penetrate the patient's skin and provide an entry for the support needle which is then advanced

needle which is then advanced through the introducer to subsequently come into contact with the dura mater. A considered reading of Zofmann demonstrates that Zofmann does not teach that the introducer 6 is to function as a catheter for use within the dura mater. Zofmann appears to contain no indication that the introducer 6 ever enters the dura mater.

In applicant's view the Zohmann device is not directed to a structure for achieving one of the principal objectives of applicant's device, namely the efficient insertion of a larger diameter catheter into the dura mater of a patient. See paragraphs [0011], [0013] and [0030] of applicant's specification. Furthermore, given that the Zohmann device is configured to operate differently from that of applicant's claimed device, the various components of Zohmann's device differ structurally from those disclosed in applicant's claims.

Claim 1 specifically requires a hollow support needle which is positioned within the hollow bore of a flexible needle catheter. The hollow support needle is releaseably coupled to the flexible needle catheter. The hollow support needle defines a pencil point, non-cutting tip which is adapted for penetrating the patient and thereby forming an entry opening for the insertion of the assembly into the patient without cutting the tissue of the dura mater. The tip is specifically configured, accordingly to Claim 1, to create an opening within the patient having dimensions such that upon a removal of the assembly from the patient, the dura mater may readily reseal the opening. Applicant respectfully submits that the Zofmann reference neither discloses nor suggests such a hollow support needle construction.

Zofmann defines a support needle 4 which has a rounded tip. See Col. 6, lines 45- 47. Zofmann appears to contain no disclosure of a support needle 4 having a "pencil point" tip. Applicant respectfully submits that Zofmann's specific requirement that tip 54 of needle support 4 be rounded does not constitute a teaching of applicant's "pencil pointed" tip. Applicant respectfully submits that given the absence of any teaching in Zofmann of a pencil point tip for needle 4, Zofmann fails to meet the requirements of 35 U.S.C. §102 as an anticipatory reference to Claim 1 and the claims dependent thereon.

Applicant's position is further reinforced with respect to the pencil point tip by considering the operation of Zofmann's device. In the Zofmann device an introducer 6, having a sharp beveled edge, is used to penetrate the skin of the patient. As further disclosed at column 8,

lines 15-20, Zohmann's "sharp, hollow introducer [70] component a few centimeters in length is used to puncture the [patient's] skin."

The function of the Zofmann device differs significantly from that of the instant claims in that applicant's device does not have an introducer. Instead, applicant's support needle 19 is configured to puncture the patient's dura mater. Since the catheter is coupled to the support needle, the flexible needle catheter 15 is carried along by the support needle 19 through the puncture opening created by the tip 27 of the support needle 19 in the dura mater. Since the catheter is structured to provide a smooth transition between the diameter of the tip 27 and the diameter of the catheter due to the taper 29, the pushing aside action initiated by the tip in penetrating through the dura mater without cutting the fibers and tissue of the dura mater is continued by the catheter as it enters the dura mater. In contrast in the Zofmann device, the outer component, introducer 6, is configured to puncture the patient's skin while the support needle is advanced through the body of the introducer 6 and to puncture the dura mater. See col. 8, lines 45-59 of the Zofmann reference.

In the instantly claimed device, the second support needle component 19 is housed within the outer catheter component 15 and extends outwardly from that outer component 15. The second component 19 punctures the patient by means of the pencil tip and then carries the outer component 15 through the puncture opening. Once the outer component 15 is in position, the second component can be withdrawn and the desired medicament can be administered to the patient through the outer component 15. In the Zofmann construction the introducer 6 and the catheter needle 4 must both stay in place within the patient while the anesthesia is administered through the second catheter component 4. In the instantly claimed device, the stylet 17 and the support needle 19 may both be removed once the flexible needle catheter 15 has been installed. Applicant submits that the operation of the two devices is quite different from one another.

These operational differences dictate structural component elements required to effect those operations which are quite distinctive from one another, including among which is the pencil point tip of the support needle 19. Further, applicant's claimed device requires that the support needle be releaseably coupled to the flexible needle catheter. As noted above, in the Zofmann structure the support needle 4 is slidable with respect to the introducer, otherwise the Zofmann

Zofmann device can not operate consistent with Zofmann's disclosure. Thirdly, applicants device requires a flexible needle catheter to be coupled to the support needle. As indicated above, the introducer of the Zofmann device is not a catheter. It is designed to penetrate the dura mater nor is it designed to provide a flow a medicating agent to the dura mater.

Applicant's Claim 1 also requires a flexible needle catheter which defines a hollow bore configured for the passage of fluid, e.g. anesthesia therethrough. This flexible needle catheter forms the catheter element of applicant's assembly. As noted above, this flexible needle is specifically required to be the outermost component of the three components which constitute the assembly. Given the outermost positioning of this component, this component has the largest exterior diameter as well as the largest interior diameter of any of the three components which form the assembly. As noted in applicant's specification at paragraph [0011] a principal objective of applicant's invention is the efficient installation of catheters having larger diameters than the catheters of prior devices. While applicant's claimed device clearly achieves this objective by adopting the structure set forth in Claim 1, Applicant respectfully submits that the Zofmann device does not define a structure which achieves this objective.

In Zofmann the medicating agent is delivered to the patient through the lumen defined within the support needle 4. See Col. 7, lines 24-26. It follows that Zofmann defines a structure wherein the medicating agent delivery element is the second component of the assembly as opposed to the claimed construction which places the anesthesia carrying component as the third or outermost component. By placing the medicating agent delivery carrying component between the stylet 2 and the introducer 6, Zofmann's device structurally limits the diameter of the medicating agent carrying element. Instead of maximizing the diameter of the catheter, Zofmann limits the diameter of the catheter (needle 4) by requiring that the catheter 4 have a smaller diameter than the introducer 6, i.e. in the Zofmann device, the needle 4 is positioned within the bore of introducer 6 and therefore the needle 4 must have a smaller diameter than the diameter of introducer 6. By adopting this particular arrangement of the components, Zofmann does not address the objective of applicant's claimed structure, namely, providing an assembly which facilitates the installation of the largest diameter catheter for a given puncture opening in a patient.

As noted in applicant's specification, health related concerns dictate that the size of a puncture opening to be formed in a patient during installation of a catheter must be constrained. It follows that for a given sized puncture opening, applicant's assembly will be able to install a larger diameter catheter than would be possible using the Zofmann device. In applicant's construction, the exterior diameter of the catheter element will be substantially equivalent to the diameter of the puncture opening formed in the patient. In the Zofmann construction, at best, the exterior diameter of the introducer will substantially correspond to the diameter of the puncture opening. It follows that owing to the nature of the Zofmann device, the actual diameter of the catheter must be significantly smaller than the diameter of the puncture opening since the catheter portion of the Zofmann device is housed within the introducer and must, therefore, have a signifcantly smaller diameter than the diameter of the introducer. Given the health related necessity of limiting the size of the opening to be created within the patient for purposes of installing the catheter, applicant's claimed structure which requires that the catheter portion of the assembly be positioned as the outermost component provides a means of installing larger diameter catheters in the patient and thereby facilitates the supply of larger quantities of medicating agent than would be possible using the Zofmann device. Zofmann's placement of the catheter portion of the assembly as the second component and not the outermost component precludes the Zofmann device from achieving the objective of installing the largest catheter for a given puncture opening as identified in applicant's specification.

Applicant further submits that the introducer 6 of the Zofmann device does not anticipate the flexible needle catheter of applicant's claims. The introducer of Zohmann is not "flexible" as required by applicants' claims. As disclosed at column 4, lines 24-26, Zohmann's "sharp, hollow introducer component . . . is used to puncture the [patient's] skin", which could not be done with a flexible needle as required by applicants' claims. The introducer of Zohmann is "[inserted] at the puncture point", which could not be done with a flexible needle. (U.S. Patent 6,558,353 at column 2, line 39).

As described in applicants' Specification and discussed at the interview, a flexible needle is

> "characterized as a flexible conduit having distal and proximal ends. Preferred flexible needles have sufficient transverse flexibility to accommodate patient torso bending movement, whereby substantially to reduce a patient's awareness of the presence of the device. Flexible needles typically are made from medical grade plastic materials. For example, polyester shrink tube or similar materials may be used."

(Specification, underlining added, ¶ **[0018]**).

As further described in the Specification, applicant's flexible needle is made of catheter material and has sufficient transverse flexibility to deform, *i.e.*,

> **[0036]** [t]he outermost layer of the assembly 10 is the flexible needle 15 itself. It preferably is approximately 23 g and about the length of a conventional spinal needle, although different diameters and lengths for use with different procedures is within the scope of the present invention. Conventional plastic catheter material may be used in its construction. The flexible needle material may be reinforced with a flat ribbon internal spring 45 (shown in FIG.5), an internal or external wire wrap, or other reinforcing structure. Alternative materials, and various materials in combination, also may be used to construct a flexible needle 15. Suitable catheter material produces a flexible needle 15 which is fairly stiff and has a sufficiently high tensile strength to maintain structural integrity during insertion, while in the body, and during retraction from a patient. A flexible needle 15 desirably possesses sufficient transverse flexibility to deform and accommodate patient motion to reduce irritation from the presence of a foreign body.

(Specification, underlining added, ¶ **[0036]**).

As noted above, Zofmann's introducer is intended as a means for puncturing the skin of a patient. With such a function in mind, the introducer must be rigid so as to properly effect this function. Applicant respectfully submits that to maintain that the Zofmann introducer is flexible would contradict the intended purpose of the Zofmann introducer. In view of this consideration, applicant respectfully submits that Zofmann fails to teach a flexible needle catheter limitation set forth in applicant's claims

All of the pending claims have been amended to require a pencil point piercing tip on the support needle. In view of this amendment, applicant respectfully submits that all of the pending claims distinguish over the Zofmann reference under the provisions of 35 U.S.C. §. 102. Accordingly, withdrawl of that rejection is respectfully requested.

In view of these, applicant maintains that the instant Claim 1, and the claims dependent thereon, distinguish over the Zofmann reference.

Claims 5 and 21 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Zohmann in view of Kreuzer et al. (US Patent 5,116,323). Applicant respectfully traverses the rejection. Kreuzer has been cited for its teaching of a luer lock connection . Applicant respectfully submits that Kreuzer does not supply teachings which rectify all of the difficiencies noted above with respect to the Zofmann reference. As a result applicant respectfully maintains that the amended claims distinguish over Zofmann and Kreuzer, both individually and in combination.

Claim 28 stands rejected under 35 U.S.C.§ 103 as being allegedly obvious over Zofmann. Applicant respectfully traverses the rejection. Claim 28 has been amended to require that the support needle have a pencil pointed tip. As noted above, Zofmann does not teach such a tip nor does Zofmann suggest such a tip. In the absence of such a taching or suggestion, applicant respectfully submits that the amended claim 28 distinguishes over Zofmann.

New claims 29-34 depend directly or indirectly from Claim 1 and therefore include all of the limitations of Claim 1. It follows that all of the arguments advanced above with respect to Claim 1 are equally applicable to Claims 29-34. Claim 29 includes the further limitation that the flexible needle catheter is tapered such that the exterior surface of the catheter transitions smoothly to the exterior surface of the support needle. This limitation follows from the nature of the interaction of the support needle and the catheter. As noted above, the support needle first contacts the skin of the patient and punctures the skin. As the support needle is inserted into the patient, the support needle carries the catheter along on its outer surface. As the catheter comes into contact with the patient's dura mater, the claimed taper on the distal or leading edge of the catheter assists the entry of the catheter into the puncture opening formed in the patient's dura

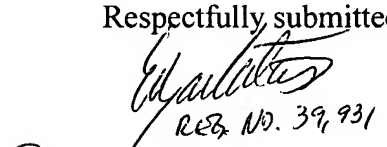
mater while simultaneously avoiding the cutting of the dura mater tissue. Applicant respectfully submits that the claimed taper is not disclosed nor suggested by the Zofmann reference. As noted above, the nature of the operation of the Zofmann device is distinctly different from that of the instant claimed device. Given the function of the introducer 6 of Zofmann there does not appear to be a need for such a taper on the catheter so as to ease the catheter through the opening formed by the introducer. In the case of the Zofmann device, the introducer would form an opening through the patient's skin which would be larger than the exterior diameter of the support needle 4. It follows that there would not be a need for a taper to ease the support needle through the puncture opening.

Claims 30 and 31 are directed to the additional limitation of a reinforcement member being positioned on the distal end of the catheter. Since the support needle and the catheter 15 are coupled together, the catheter 15 is held in a fixed orientation relative to the support needle as the support needle is inserted into the dura mater. As the leading edge of the catheter initially contacts the dura mater significant forces are applied to the leading edge by the dura mater tissue. In order to avoid a peeling back of the leading edge of the catheter and the consequent disengagement of the leading edge from the exterior surface of the support needle, the applicant, in some embodiments of the invention provides for a reinforcement member on or proximate the leading edge of the catheter. The Zofmann reference does not appear to disclose such a reinforcement member. In view of the absence of such a member, applicant submits that the instant claims 30 and 31 distinguish over the Zofmann reference.

CONCLUSION:

In view of the above considerations, applicant respectfully requests reconsideration of the claims of his application.

Respectfully submitted,



FOR: Laurence B. Bond
Registration No. 30,549
Attorney for Applicant(s)
TRASKBRITT, P.C.
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

Date: 26 January 2009
LBB/ll:csw